

Pathogens on the Hands of Hospitalized Patients

By: Taylor Truesdell

The Ohio State University College of Nursing

2017

Presented in partial fulfillment for the degree of Bachelor of Sciences with Honors in
the College of Nursing at The Ohio State University

Readers: Timothy Landers, PhD, RN, CNP, CIC, FAAN, Advisor

Kristine Browning, PhD, RN, CNP, FAANP

Acknowledgements

I want to recognize those people who helped me finish this project. I would first like to acknowledge my advisor Timothy Landers who assisted me and guided me from the beginning of this project. I would also like to thank Anthony Dent for his assistance in data collection and for his work in the laboratory. Finally, I would like to recognize The Robert Wood Johnson Foundation Nurse Faculty Scholarship Program (Grant #70320, Landers, PI) for supporting this study. A personal thanks to my classmates within the nursing honors program and my family for supporting and encouraging me in all that I do.

Abstract

Hand hygiene is recognized as the most important measure to prevent the transmission of infection. Despite evidence that infections can be transferred from contact with a patient's skin or the environment, little research has been directed toward patient-centered hand hygiene. The purpose of this study is to analyze the relationship between patient characteristics and the presence of pathogens on patients' hands.

This cross-sectional, observational study collected bacterial samples and demographic data from 22 adult medical-surgical patients at The Ohio State University Wexner Medical Center East. Bacteria were collected using glove juice sampling procedures. Samples were then serially diluted, plated, and incubated. Aerobic colonies were counted using standard counting procedures and were statistically analyzed. Pathogen specific confirmation was performed using appropriate confirmatory tests, such as gram staining and selective media. Patient demographic data, such as sex, age, ethnicity, length of stay, admitting diagnosis, and isolation precautions, were abstracted from the electronic health record. The relationship between patient data and bacterial presence was analyzed using chi-squared tests.

Results show that 86% (19/22) of patients were positive for *S. aureus*, 36% (8/22) were positive for MRSA, 86% (19/22) were positive for *C. difficile*, 24% (5/21) were positive for *C. difficile* using UV light analysis, and 30% (4/13) were

positive for VRE. The average number of colony forming units per mL of solution was 8.59×10^2 .

An increased length of stay was not associated with an increased bacterial load. There was no relationship between infectious diagnosis or isolation precautions and bacterial load. A lack of association between patient characteristics and bacterial load may be due to a lack of long-term follow-up with patients and a small sample size.

The results of this study suggest that a high percentage of patients' hands are positive for infectious organisms such as *S. aureus*, MRSA, *C. difficile*, and/or VRE. Patient hand hygiene protocols could decrease the transmission of infection, resulting in better patient outcomes and a decrease in healthcare costs.

Chapter I: Statement of the Problem

Hand hygiene is recognized as the most important measure to prevent the transmission of infection. In U.S. acute care hospitals, 4.0% of inpatients had at least one healthcare-associated infection (HAI), with an estimate of 721,800 cases in 2011 (Magill et al., 2014). HAIs contribute to high morbidity and mortality, and cost the U.S. healthcare system between \$5.7 and \$6.8 billion annually (Scott, 2009). As a result, the Centers for Disease Control and Prevention and the World Health Organization have initiated campaigns to increase the hand hygiene of healthcare workers (WHO, 2009).

While hand hygiene has been promoted for healthcare workers, little attention has been paid to patients. Very limited research and guidelines exist patient hand hygiene. Patients' hands could be a key element in decreasing the transmission of infections.

In order to better understand the role of patients' hands in the transmission of infections, several factors must be analyzed. The amount and type of bacteria present on patients' hands, factors that contribute to bacterial contamination, patients' attitudes towards hand hygiene, and the best methods and recommendations for patient hand hygiene must be assessed.

In order to decrease infections, it is also important to consider how infections are transmitted. Bacteria that cause infection are transmitted from person to person via the chain of infection (Figure 1). Transmission of infection occurs as a result of interactions between the infectious agent, a vulnerable host, and the environment.

More specifically, transmission of disease occurs when an infectious agent leaves its reservoir or host through a portal of exit, travels by a mode of transmission, and enters through a portal of entry into a susceptible host (Dicker, Coronado, Koo, & Gibson, 2012). Hand hygiene is critical to breaking this chain of infection, as direct skin contact between healthcare workers and patients can spread infectious microorganisms.

The purpose of this study is to analyze the relationship between patient characteristics and the presence of pathogens on patients' hands. The two specific aims addressed were:

Aim 1: Determine the type and number of bacteria present on patients' hands.

Aim 2: Analyze the relationship between bacterial load and a) age, b) gender, c) ethnicity, d) length of stay, e) infectious diagnosis, and f) isolation precautions.

Identifying the presence of bacteria associated with HAIs will provide important evidence to support efforts to reduce HAIs through patient-centered hand hygiene. Analyzing the relationship between bacterial load and patient characteristics is valuable in determining risk factors for bacterial presence on patients' hands. Potential risk factors for bacterial contamination include increased length of stay in hospitals and an infectious disease diagnosis. In addition, age, ethnicity, and race can be analyzed as potential risk factors. By identifying risk

factors for bacterial presence, we can target patients who are at the greatest risk for spreading and contracting infections.

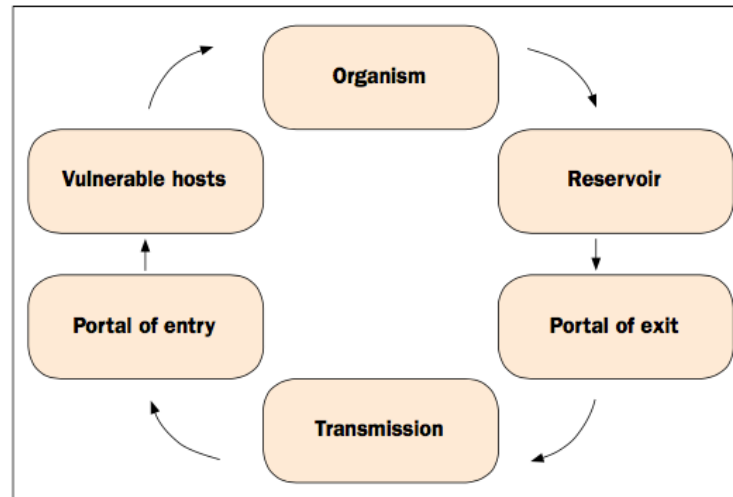


Figure 1. Chain of Infection (Cole, 2012)

Chapter II: Review of the Literature

Introduction

A wealth of research exists on healthcare worker (HCW) hand hygiene. However, very limited research and guidelines exist for hand hygiene of patients. Patients' hands could be a key element in the transmission of infections, which indicates a need for further research on patient hand hygiene behaviors and healthcare-associated infections (HAIs).

Patient hand hygiene compliance

Measurement of hand hygiene can give valuable information about hand hygiene behavior in hospitalized patients. However, there are few studies on patient hand hygiene performance. A cross-sectional observational study of hospital

inpatients found that patients performed hand hygiene during 29.7% of bathroom visits, 39.1% of mealtimes, 3.3% of kitchen visits, 2.9% of room entries, and 6.7% of room exits (Srigley, Furness, & Gardam, 2014). One study conducted at a long-term care facility unit found that hand hygiene was only performed during 2% of mealtime opportunities (O'Donnell et al., 2015). However, this percentage increased to 85% after interventions, which included education on importance of hand hygiene and more accessibility of hand-hygiene products (O'Donnell et al., 2015). Since handwashing is the number one intervention in the prevention of infection, poor patient hand hygiene could be a serious contributing factor to the spread of infection in the hospital setting (Centers for Disease Control and Prevention, 2002; World Health Organization, 2009).

While research on methods to increase patient hand hygiene compliance is limited, much research has been conducted on healthcare-worker hand hygiene compliance. According to the literature, HCWs hand hygiene compliance rates are around 40% to 50% (Al-Tawfiq, Abed, Al-Yami, & Birrer, 2013; Erasmus et al., 2010; Watson, 2016). Interventions found to have improved these rates include staff education, hand hygiene signage, available alcohol-based hand rubs, hand hygiene compliance monitoring, setting hand hygiene compliance goals, and leadership commitment (Al-Tawfiq et al., 2013). Further research is needed to determine whether interventions such as these would increase hand hygiene compliance of patients.

Factors influencing patient hand hygiene

Patients' knowledge and attitudes, patients' physical and cognitive impairments, and the accessibility of products can influence patient hand hygiene. A survey of long-term care facility residents found that barriers to hand hygiene performance were lack of awareness of all available hand hygiene products, difficulty in using these products, and lack of assistance with hand hygiene (O'Donnell et al., 2015). These findings highlight the importance of providing products that are easy to use and are highly visible.

Due to many patients' reliance on HCWs for assistance in performing hand hygiene, evaluating the perceptions, attitudes, and behavior of nurses can give insight into causes of low hand hygiene compliance. Studies have found that despite nurses having good perceptions of the importance of patient hand hygiene, nurses often do not offer assistance or encouragement to clean patients' hands (Ardizzone, Kline, Thorn, & Larson, 2013; Burnett, 2009). In fact, out of 81 observed hand hygiene opportunities, nurses only assisted patients 14 times (Ardizzone et al., 2013). These findings indicate that nurses need to be educated on the benefits of patient hand hygiene and should be regularly reminded to help their patients wash their hands.

Microbiological studies of patients' hands

Infectious organisms residing on patients' hands may be transferred to their surrounding environment, to healthcare workers, to other patients, and even to other areas of their own bodies that are at a high-risk for infection (Landers, Abusalem, Coty, & Bingham, 2012). While there is currently only limited evidence of

the role of patients' hands in the spread of HAIs, studies indicate that patients do carry hospital-associated pathogens on their hands (Itsenes et al., 2013, Larson et al., 2000).

In one study, cultures were taken from the hands of 100 medical-surgical patients. Fourteen were positive for *Clostridium difficile*, 14 were positive for methicillin-resistant *Staphylococcus aureus* (MRSA), 9 were positive for vancomycin-resistant *Enterococcus* (VRE), and 11 were positive for *Acinetobacter* species (Istenes, Bingham, Hazelett, Fleming, & Kirk, 2013). In addition, 24 patients' hands were positive for gram-negative organisms. Overall, 39% of patients were contaminated with at least one infectious organism (Istenes et al., 2013). In another study that compared organism colonization of ICU inpatients and chronically ill outpatients, ICU patients were more likely to have high counts of colony-forming units on their arms (Larson et al., 2000). Remarkably, MRSA was isolated only from inpatients. Larson et al. (2000) concluded that these results indicate an increase of multiple-antibiotic resistant organisms in hospitals. While these studies both show the prevalence of patient hand contamination, neither analyzed the relationship between patient hand contamination and the incidence of HAIs.

Patient hand hygiene and healthcare-associated infections

According to The Centers for Disease Control and Prevention (2016), in 2011 there were an estimated 722,000 healthcare-associated infections in U.S. acute care hospitals, of which about 75,000 patients died. HAIs are still a leading cause of disease and death. The prevention of these infections has been the topic of many

research studies and healthcare campaigns. Several of these studies have analyzed the effect of patient hand hygiene on healthcare-associated infection rates. In a small community hospital, a yearlong trial of systematic handwashing of all patients and visiting relatives resulted in a decrease of MRSA infections by 51% (Gagné, Bédard, & Maziade, 2010). In addition, MRSA mortality decreased from 0.7 cases per thousand admissions to 0.2 cases (Gagné et al., 2010). In a larger scale study of four hospitals in Hong Kong, implementation of directly observed patient hand hygiene before mealtimes and medication administration reduced multiple-drug-resistant *Acinetobacter baumannii* (MRAB) infections (Cheng et al., 2015). MRAB bacteremia was reduced from 14 cases in 2013 to one case in 2014, and nonbacteremic MRAB was reduced from 106 cases to 34 cases (Cheng et al., 2015). Another study expanded their *Clostridium difficile* reduction strategy to include pre-meal patient hand hygiene (Pokrywka et al., 2014). This resulted in a reduction of *Clostridium difficile* infections from 10.45 per 10,000 patient days to 6.95 per 10,000 patient days (Pokrywka et al., 2014).

These studies found that patient hand hygiene decreased the incidence of HAIs. While *Clostridium difficile*, MRSA, and MRAB were the focus of these studies, patient hand hygiene could also decrease the incidence of other nosocomial infections, such as VRE. Implementation of patient hand hygiene programs may not only result in decrease in patient morbidity and mortality, but also decrease healthcare costs.

Conclusion

Research has found that patients' hands contain pathogens, and yet patient hand hygiene compliance is incredibly low. Studies including the implementation of patient hand hygiene protocols have resulted in a decrease in HAIs. However, research focusing on patient hand hygiene is still limited. More studies on patient hand hygiene behaviors, the reduction of HAIs, and the best methods of patient education are still needed. In addition, future research should be done on recommendations for the timing of patient hand hygiene.

Chapter III: Methodology

Research Design

This was a descriptive cross-sectional study of the presence of pathogens on the hands of hospitalized patients. The study was approved by The Ohio State University Institutional Review Board (IRB) (Appendix A), the Institutional Biosafety Committee (IBC) (Appendix B), and the Health Information System Access Review Committee (HISARC) (Appendix C). Research staff was trained in data management and responsible research practices.

Population and Sample Design

The population of interest is adult medical-surgical patients. For this study, subjects were recruited from a medical-surgical unit at The Ohio State University Wexner Medical Center East. Inclusion criteria for this study included patients who were English-speaking, alert and oriented, and able to give verbal consent. A total of 22 patients were sampled for this study.

Nurses on the unit made patients aware of the opportunity to participate in the study and gave the research team a list of patients who met these inclusion criteria. Research assistants informed the patients about the study, procedures and risks and answered any patient questions. Patients gave written consent to participate in this research study and received copies of the consent to participate in research form (Appendix D) and the authorization to use personal health information in research form (Appendix E).

Data Collection Procedures

Bacteria were collected from the hands of patients using the glove juice sampling procedure. Trained research assistants conducted this procedure at the bedside. A nitrile glove was placed on the patient's hand. Seventy-five mL of sampling solution was added to the glove and secured above the wrist. The sampling fluid was formulated to remove bacteria from the skin without promoting or inhibiting bacterial growth, making this a reliable and valid means to measure bacteria on hands. The research assistant uniformly massaged all surfaces of the hand for 1 minute, paying attention to the fingers. A 3 to 5 mL sample of fluid was aseptically retrieved from the glove by pulling the glove away from the wrist, inserting a pipet into the fingers of the glove and withdrawing fluid. (ASTM, 1996).

These samples were returned to the lab and assigned an in-house Laboratory Routing Number unconnected to the medical record number or any other identifying information. Microorganisms from these samples were cultured in the lab. Solutions recovered from the glove juice sampling solution were serially diluted

and plated. These plates were labeled and incubated in the lab. Standard plate counting procedures were used to count total aerobic bacterial colonies. Pathogen specific confirmation was performed using appropriate confirmatory tests, such as gram staining and the use of selective media.

In order to obtain baseline patient characteristics, patient data was abstracted from medical records using the electronic health record. Age, gender, ethnicity, date of admission, and date of discharge were extracted from the patient record. The presence of an infectious diagnosis was considered positive for patients whose admitting diagnosis was infectious (such as pneumonia, sepsis, and wound infection) and patients whose chief complaint and assessment data were indicative of infection (such as fever with evidence of leukocytosis). Physicians' orders were reviewed to determine whether a patient was placed under isolation precautions.

Data Collection Instruments

Serial dilutions of the sampling solutions were made using Oxoid™ Tryptone Soya Broth, Hampshire, England. Five different selective media were used to determine the presence of specific pathogens in these solutions. Remel™ Tryptic Soy Agar was used for aerobic colony counts (Figure 2). BD BBL™ Mannitol Salt Agar, Becton, Dickinson and Company, was used to detect *S. aureus* (Figure 3). Oxoid™ Oxacillin Resistant Screening Agar Base was used to detect MRSA (Figure 4). BD BBL™ MacConkey Agar, Becton, Dickinson and Company, was used to detect VRE (Figure 5). CHROMagar™ *C. difficile*, Paris, France, was used to detect *C. difficile* (Figure 6).

Patient data was collected by an authorized research assistant using the electronic health record and by interviewing patients to complete a background information questionnaire (Appendix F).

Data Analysis

Demographic variables were collected for each subject. Number and percent positive for each organism were calculated. Sampling day was categorized into day 1, day 2-6, or greater than 6 days. Two investigators reviewed diagnosis codes and the presence of an infection diagnosis (pneumonia, sepsis, UTI) was noted. Gender, ethnicity, age, infection or isolation, and length of stay in relationship to any positive bacterial culture were analyzed using chi-squared tests. SPSS v.23 was used for data entry and statistics. The level of statistical significance for all analyses was set at $p>0.05$.

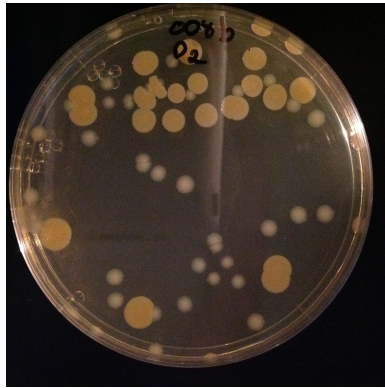


Figure 2. Aerobic colonies on tryptic soy agar

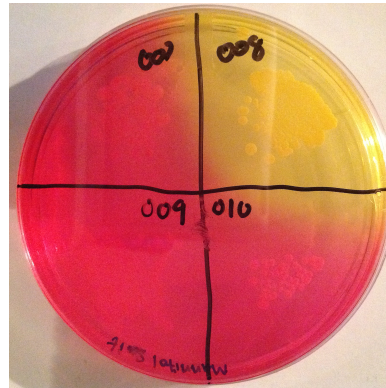


Figure 3. *Staphylococcus aureus* on mannitol salt

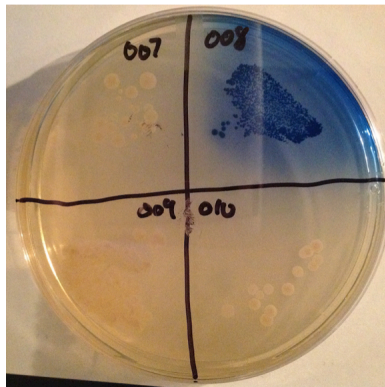


Figure 4. MRSA on oxacillin resistant screening agar

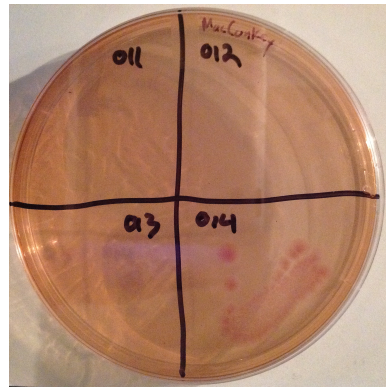


Figure 5. VRE on MacConkey agar

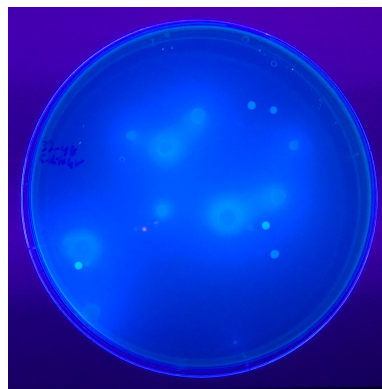


Figure 6. *Clostridium difficile* on CHROMagar™

Figure Legend: MRSA – Methacillin-resistant *Staphylococcus aureus*; VRE – Vancomycin-resistant *enterococci*

Chapter IV: Results

Twenty-two subjects were included in this study. Patient characteristics are shown in Table 1.

Table 1. Patient Characteristics (n=22)

Age, mean years \pm SD, range	51.7 \pm 16.1, 23-83
Gender:	
Male, n (%)	12 (54.5%)
Female, n (%)	10 (45.5%)
Ethnicity:	
Caucasian, n (%)	7 (32%)
African American, n (%)	15 (68%)
Date of sampling, mean days \pm SD, range	2.9 \pm 3.7, 0-15
Infectious Diagnosis, n (%)	8 (36%)
Isolation precautions, n (%)	2 (9%)

Results of bacterial sampling showed that 86% (19/22) of patients were positive for *S. aureus* 36% (8/22) were positive for MRSA, 86% (19/22) were positive for *C. difficile*, 24% (5/21) were positive for *C. difficile* using UV light analysis, and 30% (4/13) were positive for VRE. Bacteria present on patients' hands are shown in Table 2. The number of patients found to have at least one infectious organism was 95.5% (21/22). In 16 patients, the average number of colony forming units per mL of solution was 8.59×10^2 .

Table 2. Bacterial Presence on Patients' Hands (n = 22)

Bacteria	% (number)
<i>Staphylococcus aureus</i>	86% (19/22)
Methicillin-resistant <i>Staphylococcus aureus</i>	36% (8/22)
<i>Clostridium difficile</i>	86% (19/22)
<i>Clostridium difficile</i> UV light	24% (5/21)
Vancomycin-resistant <i>enterococci</i>	30% (4/13)

The number of days a patient had been hospitalized when sampled varied. The number of patients sampled on day of admittance or first full day was 13/22 (59.1%), on days two through six was 7/22 (31.8%), and on day six or greater was 2/22 (9.1%) There was no statistically significant relationship between length of stay and pathogen presence. However, a trend was noted that an increase in length of stay resulted in a decrease in percentage of patients with MRSA, VRE, and *C. difficile*. The relationship between date of hand sampling and bacteria presence is shown in Table 3.

Table 3. Bacterial Presence and Length of Stay

Hospital Day Sampled	≤ 1, % (n)	2 – 6, % (n)	>6, % (n)
<i>Staphylococcus aureus</i> (+)	85% (11/13)	100% (7/7)	50% (1/2)
Methicillin-resistant <i>Staphylococcus aureus</i> (+)	46% (6/13)	29% (2/7)	0% (0/2)
<i>Clostridium difficile</i> (+)	100% (13/13)	71% (5/7)	50% (1/2)
<i>Clostridium difficile</i> UV light (+)	33% (4/12)	14% (1/7)	0% (0/2)
Vancomycin-resistant <i>enterococci</i> (+)	50% (2/4)	29% (2/7)	0% (0/2)

There were no statistically significant relationships between infectious diagnosis or isolation precautions and pathogen presence. Pathogen presence by infectious diagnosis and isolation are shown in Table 4.

Table 4. Bacterial Presence and Infectious Diagnosis or Isolation, n (%)

		Infectious Diagnosis			Isolation		
		Y	N	p-value	Y	N	p-value
<i>Staphylococcus aureus</i>	Positive	7 (88%)	12 (86%)	0.91	2 (100%)	17 (85%)	0.56
	Negative	1 (13%)	2 (14%)		0	3 (15%)	
Methicillin-resistant <i>Staphylococcus aureus</i>	Positive	3 (38%)	5 (35%)	0.93	1 (50%)	7 (35%)	0.67
	Negative	5 (63%)	9 (64%)		1 (50%)	13 (65%)	
<i>Clostridium difficile</i>	Positive	6 (75%)	13 (93%)	0.24	2 (100%)	17 (85%)	0.56
	Negative	2 (25%)	1 (7%)		0	3 (15%)	
<i>Clostridium difficile</i> UV light	Positive	1 (14%)	4 (29%)	0.47	0	5 (26%)	0.41
	Negative	6 (86%)	10 (71%)		2 (100%)	14 (74%)	
Vancomycin-resistant <i>enterococci</i>	Positive	2 (29%)	2 (33%)	0.85	1 (50%)	3 (27%)	0.52
	Negative	5 (71%)	4 (67%)		1 (50%)	8 (73%)	
Any positive pathogen	Positive	7 (88%)	14 (100%)	0.18	2 (100%)	19 (95%)	0.75
	Negative	1 (13%)	0		0	1 (%)	

There was no statistically significant difference found between ethnicity and bacterial load. There was a statistically significant difference between *C. difficile* and gender (70% females, 100% males, $p=0.04$), but not for other organisms. There was no statistically significant difference between age and *S. aureus*, MRSA, *C. difficile*, or VRE.

Chapter V: Conclusions and Recommendations

This study found that a large percentage of hospitalized patients have multiple infectious pathogens on their hands. It is important to note that all patients but one (21/22) were positive for at least one infectious organism. However, no statistically significant relationship was found between patient characteristics and bacterial load. Such a high number of positive bacterial findings may have resulted in a lack of statistically significant relationships. In addition, a lack of significance may be due to a lack of long-term follow-up with patients and a small sample size. A small sample size taken from one hospital unit limits the generalizability of these findings. Another limitation was that few patients were sampled later in their hospital stay (>6 days).

A further limitation of this study is that microbiological tests were run to identify only four organisms: *Staphylococcus aureus*, MRSA, *Clostridium difficile*, and VRE. Aerobic colony forming units were counted, but specific colony morphologies were not identified. Other infectious organisms present on subjects' hands could have been unidentified.

Limitations of the data collection procedure include patients presenting multiple diagnoses, but only their primary diagnosis being noted. Patients may have also had undiagnosed or developing infections. In addition, patient ethnicity was self-reported and therefore could be inaccurate.

This study indicates that a high percentage of patients' hands could be positive for infectious organisms such as *S. aureus*, MRSA, *C. difficile*, or VRE. The prevalence of bacteria present on the first two days of hospitalization indicates that pathogens may be community-acquired, not hospital-acquired. Regardless of the source of these pathogens, this data provides evidence for the adoption of patient hand hygiene protocols.

Existing research has found that patients' hands contain pathogens, and the research consistently shows that patient hand hygiene compliance remains incredibly low. The limited number of studies analyzing the implementation of hand hygiene protocols for patients resulted in a decrease in HAIs.

Patient hand hygiene could be key to further reducing the incidence of HAIs. . Further research needs to be conducted to confirm the presence of infectious pathogens in other populations of hospitalized patients. Additional research needs to be conducted to determine best practice for patient-centered hand hygiene, including methods of hand hygiene, types of hand hygiene products, and guidelines for the timing of hand hygiene. Standard protocols would need to be implemented and healthcare professionals would need to be educated and trained to implement patient-centered hand hygiene. In addition, community health professionals would

need to implement hand hygiene protocols in the community setting. Determining the association between patient hand hygiene and hospital infection rates could result in the improvement of patient hand hygiene practices. Implementing patient hand hygiene as an infection prevention measure could prevent life-threatening infections and significantly reduce healthcare costs.

Appendix A



Biomedical Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

Phone (614) 688-8457
Fax (614) 688-0366
orip.osu.edu

1/19/2015

Protocol Number: 2014H0444

Protocol Title: Patient Centered Hand Hygiene

Review Method: Expedited

Dear Timothy Landers,

On 11/19/2015, the Ohio State Biomedical IRB **APPROVED** by Expedited review your amendment for the above-referenced research. The following individuals were added or removed from the study team:

Amendment #1

ADDED:

- Taylor Truesdell
- Emily Aman

MODIFIED:

- Anthony Dent (None)

REMOVED:

- Kristopher Smedes

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. Policies, procedures, and guidance can be found on the ORRP website - orip.osu.edu. Please feel free to [contact ORRP](mailto:contact@orip.osu.edu) with any questions or concerns.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB.

Karla Zadnik, OD, PhD, Chair
Ohio State Biomedical IRB

Appendix B

10/20/2015

<https://protocol.osu.edu/OSU/Doc/07D47A8U4G9EK13OK7R4V10QU3F/fromString.html>**Institutional Biosafety Committee**1960 Kenny Road
Columbus, OH 43210-1063Phone (614) 688-8457
Fax (614) 688-0366
www.osu.eduTimothy Landers
College of Nursing
1585 Neil Ave
Columbus, OH 43210

Dear Dr. Landers:

The Institutional Biosafety Committee (IBC) has granted final approval to your IBC protocol 2013R00000047 Patient Hand Hygiene on 11/04/2013. The IBC specified that your experiments be conducted under BSL-2 containment. Work on this protocol is approved until 11/04/2014. You must submit an annual review form prior to this date to obtain continued IBC approval. You will receive an email letter as a reminder of this obligation. Should any changes take place before the next review, please submit an amendment form.

Sincerely,

*Marshall V. Williams, Jr Ph.D.*Marshall V. Williams, Ph.D.
Institutional Biosafety Chair
Institutional Biosafety Committee

<https://eprotocol.osu.edu/OSU/Doc/0/H08859V2479KF1D21JQM899F3...>



Institutional Biosafety Committee

1960 Kenny Road
Columbus, OH 43210-1063

Phone (614) 688-8457
Fax (614) 688-0366
www.omp.osu.edu

Timothy Landers
1585 Neil Ave
Columbus, Ohio 43210

Dear Dr. Landers:

Based on the information provided on the Annual Review, your IBC protocol 2013R000000047 Patient Hand Hygiene has been granted continuing approval. Final approval was granted on 10/20/2014. The IBC specified that your research be conducted under BSL-2 containment.

Sincerely,

Marshall V. Williams, Jr Ph.D.

Marshall V. Williams, Ph.D.
Institutional Biosafety Chair
Institutional Biosafety Committee

Appendix C



THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

November 16, 2015

College of Medicine
Office of Health Sciences
Administrative Offices
200 Meiling Hall
370 West 9th Avenue
Columbus, OH 43210
614-292-2220 Phone
614-688-8644 Fax
medicalcenter.osu.edu

Timothy Landers PhD, RN, CNP, CIC
Assistant Professor, Ohio State University, College of Nursing
1585 Neil Avenue
Columbus, Ohio 43210

Dear Dr. Landers,

Thank you for your participation in the Health Information Systems Access Review Committee. Based on the review completed by this Committee, you have met all of the requirements for beginning your research study "Patient Hand Hygiene". Substantive changes in the research procedures such as changes in recruitment procedures, the amount or type of information collected, or accesses requested must be approved by the Committee before they are implemented. It is the investigator's responsibility to promptly report to the Committee any serious, unexpected, or unanticipated problems involving the data collected or data storage.

Please contact Esther Chipps PhD, RN, Clinical Nurse Scientist at the Ohio State University Health System with any further questions.

Sincerely,

Esther Chipps PhD, RN
Clinical Nurse Scientist
Ohio State University Health System
Co-Chair Health Information Systems Access Review Committee,

Mary Nash, PhD, RN, FAAN, FACHE, NEA-BC
Chief Nurse Executive, Health System
Co-Chair, Health Information Systems Access Review Committee
Associate VP, Health Sciences
The Ohio State University Wexner Medical Center
Assistant Dean, OSU College of Nursing

cc: Jennifer Elliot
Kim Arcoleo

Appendix D

The Ohio State University Consent to Participate in Research

Study Title: Patient Centered Hand Hygiene

Principal Investigator: Timothy Landers, RN CNP PhD

Sponsor: Robert Wood Johnson Foundation

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

The goals of this project are:

- To get hospital patient's opinion about hand sanitizers.
- To find out what bacteria are on hospital patient's hands.
- To find out how much hand sanitizer hospital patients use.

2. How many people will take part in this study?

We will recruit 100 people for the project.

3. What will happen if I take part in this study?

In this project we will see what types of bacteria exist on your hands.

The research assistant will conduct a “glove juice” procedure in order to detect the presence of bacteria on your hands. This involves putting a glove on your hand and the research assistant will pour in a soapy liquid into the glove and rub the hand for 60 seconds.

Then the research assistant will use a small plastic suction remove 2tsps out of the glove and put in in the collection tube. The tube will be coded by a private number.

For the second part of the project, we will ask to fill out a paper survey on your impression of 4 hand sanitizers.

The glove juice procedure and hand sanitizer opinion survey should take about 45 minutes.

Hand sanitizers will be available for you during their stay. We will measure how many times you use them. The study would like to capture your experience in the hospital.

The research assistant will then return in 48 hours and he/she will repeat the glove juice procedure.

4. How long will I be in the study?

You will be in the study for 48 hours.

No long-term follow-up will be conducted.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

You may experience mild skin irritation or dryness while using the hand hygiene products and/or during the 'glove juice' sample collection procedure.

7. What benefits can I expect from being in the study?

No known benefits.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

No costs.

11. Will I be paid for taking part in this study?

You will not be paid to participate but you may keep the hand sanitizer products.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact **Timothy Landers, PhD, RN, CNP at 614-292-0309.**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Timothy Landers, PhD, RN, CNP at 614-292-0309.**

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

_____ Printed name of subject	_____ Signature of subject
	_____ Date and time
	AM/PM
_____ Printed name of person authorized to consent for subject (when applicable)	_____ Signature of person authorized to consent for subject (when applicable)
_____ Relationship to the subject	_____ Date and time
	AM/PM

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

_____ Printed name of person obtaining consent	_____ Signature of person obtaining consent
	_____ Date and time
	AM/PM

Witness(es) - *May be left blank if not required by the IRB*

_____ Printed name of witness	_____ Signature of witness
	_____ AM/PM

	<div>Date and time</div>
<div>Printed name of witness</div>	<div>Signature of witness</div>
	<div>Date and time</div> AM/PM

Appendix E

**THE OHIO STATE UNIVERSITY
AUTHORIZATION TO USE
PERSONAL HEALTH INFORMATION IN RESEARCH**

Title of the Study: Patient Centered Hand Hygiene

Protocol Number: 2014H0444

Principal Investigator: Timothy Landers

Subject Name_____

Before researchers use or share any health information about you as part of this study, The Ohio State University is required to obtain your authorization. This helps explain to you how this information will be used or shared with others involved in the study.

- The Ohio State University and its hospitals, clinics, health-care providers, and researchers are required to protect the privacy of your health information.
- You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you. Please carefully review this information. Ask if you have any questions or do not understand any parts of this notice.
- If you agree to take part in this study your health information will be used and shared with others involved in this study. Also, any new health information about you that comes from tests or other parts of this study will be shared with those involved in this study.
- Health information about you that will be used or shared with others involved in this study may include your research record and any health care records at The Ohio State University. For example, this may include your medical records, x-rays, or laboratory results. Psychotherapy notes in your health records (if any) will not, however, be shared or used. Use of these notes requires a separate, signed authorization.

Please read the information carefully before signing this form. Please ask if you have any questions about this authorization, the university's Notice of Privacy Practices or the study before signing this form.

Those Who May Use, Share, and Receive Your Information as Part of This Study

- Researchers and staff at The Ohio State University will use, share, and receive your personal health information for this research study. Authorized Ohio State staff not involved in the study may be aware that you are participating in a research study and have access to your information. If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records.

Initials/Date: _____

- Those who oversee the study will have access to your information, including the following:
 - Members and staff of The Ohio State University's Institutional Review Boards, including the Western Institutional Review Board
 - The Ohio State University Office of Responsible Research Practices
 - University data safety monitoring committees
 - The Ohio State University Office of Research.
- Your health information may also be shared with federal and state agencies that have oversight of the study or to whom access is required under the law. These may include the following:
 - Food and Drug Administration
 - Office for Human Research Protections
 - National Institutes of Health
 - Ohio Department of Job and Family Services.

The information that is shared with those listed above may no longer be protected by federal privacy rules.

Authorization Period

This authorization will not expire unless you change your mind and revoke it in writing. There is no set date at which your information will be destroyed or no longer used. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be completed.

Initials/Date_____

Signing the Authorization

- You have the right to refuse to sign this authorization. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form.
- You will not be able to take part in this study and will not receive any study treatments if you do not sign this form.
- If you sign this authorization, you may change your mind at any time. Researchers may continue to use information collected up until the time that you formally changed your mind. If you change your mind, your authorization must be revoked in writing. To revoke your authorization, please write to: Timothy Landers, PhD, RN, CNP, landers.37@osu.edu, 1585 Neil Avenue, Columbus, OH 43210, 614 292 0309.
- Signing this authorization also means that you will not be able to see or copy your study-related information until the study is completed. This includes any portion of your medical records that describes study treatment.

Contacts for Questions

- If you have any questions relating to your privacy rights, please contact: Kimberly Arcoleo, Associate Dean for Research, College of Nursing, 350 Newton Hall, 1585 Neil Avenue, Columbus, OH 43210, Arcoleo.1@osu.edu, (614) 688-3734.
- If you have any questions relating to the research, please contact: Timothy Landers, PhD, RN, CNP, landers.37@osu.edu, 1585 Neil Avenue, Columbus, OH 43210, 614 292 0309

Signature

I have read (or someone has read to me) this form and have been able to ask questions. All of my questions about this form have been answered to my satisfaction. By signing below, I permit Timothy Landers and the others listed on this form to use and share my personal health information for this study. I will be given a copy of this signed form.

Signature _____
(Subject or Legally Authorized Representative)

Print Name _____ Date _____ Time _____ AM/PM

(If legal representative, also print relationship to subject)

Appendix F

Questionnaire – Part 2: Background Information

Subject Number : _____

Interviewer : _____

<p>1. Age: _____</p> <p>2. Gender: <input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Other</p> <p>3. Religion: <input type="checkbox"/> Christianity <input type="checkbox"/> Judaism <input type="checkbox"/> Islam <input type="checkbox"/> Buddhism <input type="checkbox"/> Hinduism <input type="checkbox"/> Atheism <input type="checkbox"/></p>	<p>4. Highest Level of Education Completed:</p> <p><input type="checkbox"/> Less than High School <input type="checkbox"/> High School <input type="checkbox"/> Some College <input type="checkbox"/> College Graduate <input type="checkbox"/> Graduate School <input type="checkbox"/> Trade School</p> <p>5. Occupational Field: _____</p> <p><input type="checkbox"/> Full time <input type="checkbox"/> Part time</p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

6a. Is the subject wearing jewelry such as a ring or bracelets?

☐ No☐ Yes Please list: _____

6b. Is the subject wearing finger nail polish?

☐ No☐ Yes Please list: _____

6c. Is the subject wearing artificial nails?

☐ No☐ Yes Please list: _____

7. Do you develop rashes?

☐ No☐ Yes

8. Do you have a skin condition?

☐ No☐ Yes Please list: _____

9. How important do you think it is to use alcohol-based hand rubs?

Not Important	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Very Important
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Which of the following would prevent you from using alcohol-based hand rubs?

☐ Don't have time☐ Damaged skin☐ Not easily accessible☐ Don't want to use chemicals☐ Don't think about it

Thank you for your participation!

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